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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,390	12/03/2001	Stephen M. Zappala	16865-00011	6989
7590 08/16/2004				
Jenifer E. Haeckl, Esq. Mirick, O'Connell, DeMallie & Lougee, LLP 1700 West Park Drive Westborough, MA 01581-3941			EXAMINER EVANISKO, GEORGE ROBERT	
			ART UNIT 3762	PAPER NUMBER

DATE MAILED: 08/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/005,390	<b>Applicant(s)</b> ZAPPALA <i>on</i>	
	<b>Examiner</b> George R Evanisko	<b>Art Unit</b> 3762	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 May 2004.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 7 and 14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5/10/04.

Applicant's election with traverse of group I in the reply filed on 5/10/04 is acknowledged. The traversal is on the ground(s) that claim 1 specifically requires the use of the device for managing a patient's erectile dysfunction. This is not found persuasive because the limitations are intended use recitations, such as "adapted to be implanted in the...abdominal wall" and "adapted to be implanted at the suprapubic level", and do not specifically require the pulses generator or lead to be implanted in those locations but only require that they be "capable" of operating in those locations. A heart pacemaker could be used to reject claim 1 since the pacemaker is capable of being implanted in those locations. In addition, the apparatus as claimed can be used to practice another and materially different process not requiring selective activation by the patient, but activation by the pulse generator during sleep for training.

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-6 and 8-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, “upon selective activation by the patient” is vague and makes the claim incomplete since no element has been set forth to allow the device to be selectively activated by the patient.

In claim 4, “a high impedance” is a vague and a relative phrase which renders the claim indefinite. The term “high” is not defined by the claim and the specification does not provide a standard for ascertaining the requisite degree.

In claim 9, “a titanium shell” is inferentially included and it is unclear if the claim is positively reciting the shell. It is suggested to first set forth that the system further comprises the shell (“of claim 1, further comprising a titanium shell, wherein said power...”).

In claim 12, “a biocompatible shell” is inferentially included and “upon selective activation” is vague.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Krakovsky et al (5454840). Krakovsky shows the pulse generator, 46, battery, 40 and lead containing electrode,

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48 and is capable of meeting the functional use recitations presented in the claim since it is an implantable device with an implantable lead and electrode.

Claims 1-3, 5, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Meloy et al (6169924). Meloy is capable of meeting the functional use recitations presented in the claims, such as being implanted in certain areas, since the lead, electrode, and system are implantable.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Ardito et al (5938584). Ardito is capable of meeting the functional use recitations presented in the claims, such as being implanted in certain areas, since the lead, electrode, and system are implantable.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 5, and 10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Krakovsky et al. Krakovsky states that he uses a lithium battery LBSAR 5 which is a “high” impedance battery. In addition Krakovsky uses 2.5-5 volt pulses at a frequency of 2 Hz which is about the claimed “about 10 Hz” high frequency pulses of claims 5 and 10.

In the alternative, Krakovsky discloses the claimed invention using 2.5-5 Volt pulses and that the pulse parameters (height, frequency, etc) can be changed for each individual patient by testing (column 3) but does not disclose expressly the high impedance battery and the use of high

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frequency pulses of about 10-40 Hz. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the implantable pulse generator as taught by Krakovsky with the high impedance battery, because Applicant has not disclosed that the high impedance battery provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the lithium battery as taught by Krakovsky, because it provides a long lifetime of 5-8 years to operate the pulse generator.

Therefore, it would have been an obvious matter of design choice to modify Krakovsky to obtain the invention as specified in the claim(s).

In addition, Krakovsky provides a clear suggestion that the pulse height and frequency can be modified to determine the appropriate stimulation parameters based on the particular patient and place of stimulation. The determination of the most appropriate pulse height and frequency, such as about 10-40 Hz and 1 to 5.5 V, by routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the medical art.

Claims 6, 9, and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krakovsky.

Krakovsky discloses the claimed invention using 2.5-5 Volt pulses, that the pulse parameters (height, frequency, etc) can be changed for each individual patient by testing (column 3), and the use of other electrodes for connecting to the nerves/muscles (column 5 and 6), except for the low amplitude, high frequency pulses of 10 to 40 Hz and 1 to 5.5 Volts (claim 13), the lead with an outside diameter of 2 mm or less with extension cable/lead (claim 6), the power source and generator housed in a biocompatible titanium shell (claims 9 and 12) and the tip

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electrode comprised of an indifferent material (claims 11 and 12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable device as taught by Krakovsky, with a lead with an outside diameter of 2 mm or less with extension cable/lead, the power source and generator housed in a biocompatible titanium shell, and the tip electrode comprised of an indifferent material, such as stainless steel or platinum, since it was known in the art that implantable devices use: a lead with an outside diameter of 2 mm or less with extension cable/lead to provide a lead that is small, unobtrusive, and does not damage tissue when implanted and used in the body and provide a lead that can reach the particular area of stimulation from a remote location of the pulse generator; the power source and generator housed in a biocompatible titanium shell to provide a biocompatible housing that does not degrade in the body and is strong enough to take impacts; and the tip electrode comprised of an indifferent material, such as stainless steel or platinum, that is biocompatible and will not substantially degrade due to the pulses being delivered through the electrode.

In addition, Krakovsky provides a clear suggestion that the pulse height and frequency can be modified to determine the appropriate stimulation parameters based on the particular patient and place of stimulation. The determination of the most appropriate pulse height and frequency, such as about 10-40 Hz and 1 to 5.5 V, by routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the medical art.

***Allowable Subject Matter***

Claim 8 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.


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*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
George R Evanisko  
Primary Examiner  
Art Unit 3762

8/4/4

GRE  
August 4, 2004